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10/579,246	05/12/2006	Dariush Behnam	P71222US0	6645

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER
HUANG, GIGI GEORGIANA

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1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,246	BEHNAM, DARIUSH	
	Examiner	Art Unit	
	GiGi Huang	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-17 are present for examination at this time.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to an antioxidative flowable active ingredient. This is indefinite as it can be any utilizable active ingredient with reductant properties. Examples could include glutathione, vitamin C, vitamin E, vitamin A, enzymes such as catalase and other peroxidases, and magnesium to start. The claims do not adequately claim the subject matter for one of skill in the art to distinguish the metes and bounds of the invention.

4. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to oil. This is indefinite as it can be any oil or any component that is hydrophobic or has oily properties. Examples could include olive, grape seed, bacon fat (at higher temperatures), rendered fat, butter, waxes, propylene glycol, and corn oil to start. The claims do not adequately claim the

subject matter for one of skill in the art to distinguish the metes and bounds of the invention.

5. The term "especially antioxidative" in claims 1-7-17 is a relative term that renders the claim indefinite. The term "especially antioxidative " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This is indefinite as it can be any degree of antioxidation including none. The claims do not adequately claim the subject matter for one of skill in the art to distinguish the metes and bounds of the invention.

6. Claims 1-17 recites the limitation "viscosity of the composition is between the viscosity of the active ingredient and the viscosity of the oil". Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 and the dependent claims recite the limitation "viscosity of the composition is between the viscosity of the active ingredient and the viscosity of the oil". This is indefinite as it can be any utilizable active ingredient with reductant properties. Examples could include glutathione, vitamin C, vitamin E, enzymes such as catalase and other peroxidases, and magnesium all of which have various viscosity levels especially as some are in mineral form. The oil is indefinite as it can be any oil with any level of viscosity. Dependent on the degree of hydrogenation or temperature, viscosity levels will vary even within the oils. The claims do not adequately claim the subject matter for one of skill in the art to distinguish the metes and bounds of the invention.

7. Claim 4 recites the limitation "oleaginous portion of the composition" in claim 1. There is insufficient antecedent basis for this limitation in the claim. The composition in claim 1 is to a single oleaginous composition, not a portion of a composition. It is noted that claim 4 recites the intended use of adding the oleaginous portion to a composition that is unclear, indefinite, and an intended use that has no patentable weight in a composition claim.

8. Claims 5-16 recites the limitation "premixture" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 5-7, 9 recites the limitation "wax" in claim 1. There is insufficient antecedent basis for this limitation in the claim. The claim as written does not make clear if the wax is a further limitation as not being “further comprising” of the composition of claim 1 and is thereby read as a limitation lacking basis for claim 1.

10. The term "small" in claims 5-7 and 11-15 is a relative term that renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is inadequate distinction as to what quantity “small” would relate to. The claims do not adequately claim the subject matter for one of skill in the art to distinguish the metes and bounds of the invention.

11. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a composition comprising about one

part active ingredient and multiple parts of premixture. It is unclear what the proportions are, what is the active ingredient, what "parts" is a unit of, and what the composition is actually composed of. The term "about one part" is also relative and indefinite as it is the unit of measurement and it is unclear what the quantity is. The claims do not adequately claim the subject matter for one of skill in the art to distinguish the metes and bounds of the invention.

12. The term "part" in claims 8 and 16 is a relative term that renders the claim indefinite. The term "part" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is inadequate distinction as to what quantity "part" would relate to. The claims do not adequately claim the subject matter for one of skill in the art to distinguish the metes and bounds of the invention.

13. The term "multiple" in claims 8 and 16 are a relative term that renders the claim indefinite. The term "multiple" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is inadequate distinction as to what quantity "multiple" would relate to. It could be any number greater than one, e.g. 5, 10, 200. The claims do not adequately claim the subject matter for one of skill in the art to distinguish the metes and bounds of the invention.

14. Regarding claims 8-9 and 15-16, the phrase "especially" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

15. Regarding claims 10-16, the phrase "in such a way" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

16. Claims 11-15 recites the limitation "wax" in claim 10. There is insufficient antecedent basis for this limitation in the claim. The claim as written does not make clear if the wax is a further limitation as not being “further comprising” of the composition of claim 10 and is thereby read as a limitation lacking basis for claim 10.

17. Regarding claim 12, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

18. Regarding claim 13, the phrase "or similar" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "or similar"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

19. Claim 15 recites the limitation "oleaginous portion of the pre-mixture" in claim 11 dependent on claim 10, dependent on claim 1. There is insufficient antecedent basis for this limitation in the claim. The composition in claim 1 is to a single oleaginous composition, not a portion of a composition or a premixture.

20. Claim 17 provides for the use of a composition in claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what

method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

21. Claims 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 10-16 are methods of making improperly dependent on product claim 1. It is unclear what the claimed subject matter is for the product and methods of making.

22. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 17 is a use claim improperly dependent on product claim 1. It is unclear what the claimed subject matter is for the product and methods of use.

23. The claims are examined with their broadest interpretation.

24. Applicant is reminded not to include new matter.

Claim Rejections - 35 USC § 102

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

26. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Abbiati (WO00/08061).

Abbiati teaches a composition comprising hyaluronic acid, propylene glycol, glyceryl stearate (emulsifier), shea butter (shea butyrum – a fat/oil), avocado butter (persea gratissima – a fat/oil), cera alba (beeswax), tocopherol (vitamin E- antioxidant), retynyl palmitate (Vitamin A - antioxidant), ascorbic acid (Vitamin C – antioxidant), and polysorbate 20 (emulsifier). The composition is for an anti-aging cream. The preparation of the cream involves the emulsification of all water-soluble excipients in one turboemulsifier, and all oily excipients in the other turboemulsifier, except for lysine hyaluronate, elastin, collagen, tocopherol and fragrance. Both solutions were stirred with increasing temperatures until 80°C, untied, and mixed while lowering the temperature down to 25°C (passing through the limitation of about 40oC to about 60°C). All remaining excipients are added (tocopherol- antioxidant) except lysine, heated, stirred, cooled while stirred, adding the lysine hyaluorate (Page 13, line 22, Page 14, line 1-25, Page 15, lines 1-25, Page 16, lines 1-15, Claims 21-24).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

27. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Clum et al. (U.S. Pat. No. 5,652,263).

Clum et al. teaches a skin care composition comprising retinoids (vitamin A and derivatives – antioxidants), propylene glycol, polysorbates (emulsifiers), oleic acid (oil), beeswax, stearoxytrimethylsilane (wax), and ascorbic acid (Vitamin C – antioxidant). The preparation of the cream involves the emulsification of all water-soluble excipients in one container, the retinoid mixture including the antioxidants mixed in a second container, and all oily excipients in the third container including a prepared mixture of oleic acid, myristyl myristate, wax, and beeswax among others. The aqueous and oil solutions were stirred with increasing temperatures until about 80°C, combined, and mixed while lowering the temperature down to about 50°C (within the limitation of about 40°C to about 60°C). The antioxidants were added, stirred, and then cooled while stirring to room temperature. While Example I and IV utilized Polysorbate 61, Example XV utilized Polysorbate 20 and one of skill in the art would have immediately envisioned its use instead of Polysorbate 61 as they are analogous products (Col. 7-10, Example I, Col. 8, Table 1, Col. 13-15, Example IV and Table 4, Col. 21-22, Example XV).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

29. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behnam (U.S. Pat. No. 6774247) in view of Sheppard et al. (U.S. Pat. No.4847078).

Behnam teaches a composition comprising ascorbic acid with a polysorbate, method of manufacture, and applications thereof. The composition comprises of ascorbic acid, polysorbate including polysorbate 20 and 80 (emulsifiers), antioxidants including tocopherol, and oils (sunflower, thistle, linseed oil, etc). The process of manufacture involves dissolving ascorbic acid in water and polysorbate with oil, heated to about 60°C and brought to room temperature. Variations exemplified include the incorporation of the solubilisate mixed with a tocopherol solubilisate, heated to about 50°C while mixing. The product can be employed as an antioxidant for foodstuff colorants, oils cosmetics, pharmaceuticals, and other products (Abstract, Col. 2, lines 7-48, Col. 3, lines 10-45, Example 1, Col. 4, Example 2-4, Col. 5, Example 4, Example 5, Claims 1-17).

Behnam does not expressly teach the incorporation of wax or beeswax.

Sheppard et al. (U.S. Pat. No. 4870478) teaches that wax compounds are useful as emollients and humectants in topical applications. Sheppard teaches that they aid in softening, moisturizing, lubrication of the skin. The addition of the wax compounds also promotes the production and application of a cream so as to not irritate the skin through abrasion. The preferred waxes are cetyl alcohol, stearyl alcohol, beeswax, natural or

synthetic candelilla, carnauba, jojoba oil, and ceresine. Beeswax was exemplified in examples 5 and 10 (Col. 2, lines 35-45, Col. 8, Example 5, Col. 10, Example 10).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate wax or beeswax, as suggested by Sheppard, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because in creating a topical formulation, that is soft, moisturizing, lubricating, and easy to apply is highly desirable. Beeswax is commercially available, as are other waxes, and dependent on pricing and humectant properties, one of skill in the art would use what was most cost effective as the products are analogous.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

30. Claims 1-17 are rejected.

31. The following pertinent pieces are art were not relied on in this office action but are worthy of note: Hernandez et al. (U.S. Pat. No. 6110477), Mitchnick et al. (U.S. Pat.

No. 6103267), Kraechter et al. (U.S. Pat. Pub. No. 20050158396), Greene et al. (U.S. Pat. No. 5155244), and Ford et al. (U.S. Pat. No. 5607707).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200